

### **Remarks**

The Office Action mailed April 11, 2007 has been received and reviewed. Claims 1-18 and 20-78 are pending and under consideration. Claims 46 and 71 have been amended to correct obvious typographical errors. Reconsideration and withdrawal of the rejections are respectfully requested.

### **Rejection under 35 USC §102**

Claims 1-18 and 20-78 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Number 6,153,252 (Hossainy). Claims 1-18 and 20-78 also stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Number 6,110,483 (Whitbourne). Applicants respectfully traverse.

MPEP §2131 states, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Applicants' claims recite methods that includes some variation of selecting a second polymer to be miscible with a first polymer provided elsewhere in the claim in order form a miscible blend particularly suited for tunable delivery of an active agent. Applicants respectfully submit that neither Hossainy nor Whitbourne set forth each and every feature recited in Applicants' claims. Specifically, Applicants submit that neither Hossainy nor Whitbourne set forth the conscious, intentional, deliberate step of selecting a second polymer to be miscible with the first polymer.

Hossainy teaches polymer coated stents and processes for coating stents. Hossainy teaches a variety of considerations that can be used to select polymers: tackiness, adherence, deformability, toughness, elasticity, melting point (col. 5, lines 39-51), and active agent release rate (col. 7, lines 18-55 and col. 9, lines 26-32). Hossainy neither expressly nor inherently teaches selecting polymers based on their miscibility.

Whitbourne teaches medicated coatings that can include polymer blends particularly suited for controlling the lubricity, stability, swelling, flexibility, adhesion, and

resistance to removal by wet abrasion (col. 9, lines 29-32). Whitbourne neither expressly nor inherently teaches selecting miscible polymers particularly suited for controlling the release of active agents.

In contrast, Applicants' claims recite methods that include expressly, intentionally, and consciously selecting a second polymer *to be* miscible with the first polymer, as opposed to merely selecting a second polymer "that is" miscible with the first polymer. The claimed methods include the conscious selection of the second polymer based on miscibility with the first polymer. Thus, the present claims recite a *cognitive and discretionary* step that was unknown and, therefore, impossible prior to Applicants' disclosure.

Hossainy and Whitbourne merely recite long laundry lists of general classes of polymers, some of which might be miscible with others. In contrast, Applicants claim methods that include selecting specific types of polymers *based on* their miscibility. In the absence of evidence that one of the polymer selection criteria specified in Hossainy or Whitbourne *necessarily* results in selection of miscible polymers, neither Hossainy nor Whitbourne can anticipate Applicants' claims.

The Final Office Action deems the remarks above unpersuasive, stating that each of Hossainy and Whitbourne teaches methods of forming coatings on medical devices that can be comprised of the same polymer blend as recited in Applicants' claims, and that since the polymers are the same it is inherent they would have the same solubility parameters and differences in solubility parameters recited in Applicants' claims. The Office Action further states that "It appears as though applicants are claiming an unknown property...of an old combination" and concludes that claiming a new use, new function or unknown property which is inherently present in the prior art does not necessarily make a claim patentable (Final Office Action, page 3 with respect to Hossainy, pages 3-4 with respect to Whitbourne). Without agreeing to the underlying premise that the polymer blends described in Hossainy or Whitbourne are the same as those recited in Applicants' claims, this analysis wholly ignores the fact that Applicants' claims are not directed to the polymer blends themselves, but are instead directed to the *methods* by which the coatings and, in particular, the miscible polymer blends are formed.

Thus, the similarity or dissimilarity of the polymer blends recited in Applicants' claims compared to those described in Hossainy and/or Whitbourne is irrelevant to determining the patentability of Applicants' claims.

The relevant inquiry is whether Hossainy and/or Whitbourne set forth each and every step recited in Applicants' claims for the preparation of the polymer blends. Hossainy and Whitbourne do not. Applicants have not merely discovered that certain polymer blends are miscible and are not merely claiming miscible polymer blends. Instead, Applicants have discovered that by consciously and deliberately selecting a second polymer to be miscible with the first polymer, one can prepare a miscible polymer blend that can provide tunable delivery of an active agent. Applicants claim methods that include the cognitive selection of the second polymer based on the identity and solubility parameters of the first polymer. It is this selection of the second polymer that is missing from Hossainy and Whitbourne.

Neither Hossainy nor Whitbourne teaches, expressly or inherently, the step of selecting the second polymer to be miscible with the first polymer and, therefore, neither document can anticipate Applicants' claims. The Office has failed to identify any teaching in either Hossainy or Whitbourne that sets forth selecting a second polymer to be miscible with the first polymer.

Applicants submit that the rejection of Applicants' claims under 35 U.S.C. §102(b) as being anticipated by Hossainy or Whitbourne is improper. Applicants respectfully request that the rejection of claims 1-18 and 20-78 under 35 U.S.C. §102(b) be withdrawn or, in the alternative, that the Office indicate the specific location of the teaching in Hossainy or Whitbourne that sets forth the intentional selection of a second polymer to be miscible with the first polymer.

### **Rejection under 35 USC §103**

Claims 1-18 and 20-78 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Hossainy. Claims 1-18 and 20-78 also stand rejected under 35 U.S.C. §103(a) as being unpatentable over Whitbourne. Applicants respectfully traverse.

MPEP §2143 states that in order to establish a *prima facie* case of obviousness, three criteria that must be met:

- (i) there must be a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
- (ii) there must be a reasonable expectation of success; and
- (iii) the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Applicants submit that Hossainy fails to set forth a *prima facie* case of obviousness for claims 1-18 and 20-78 because, at least, Hossainy fails to set forth each and every element of the claims. Applicants further submit that Whitbourne fails to set forth a *prima facie* case of obviousness for claims 1-18 and 20-78 because, at least, Whitbourne fails to set forth each and every element of the claims. The deficiencies of the teachings of Hossainy and Whitbourne are set forth above with regard to the rejections under 35 U.S.C. §102.

The Final Office Action deems Applicants' remarks unpersuasive, restating remarks based on the alleged similarity of polymer blends recited in Applicants' claims compared to those described in Hossainy and Whitbourne. As stated in the immediately preceding section, this analysis wholly ignores the fact that Applicants' claims are not directed to the polymer blends themselves, but are instead directed to *methods* by which the coatings and, in particular, the miscible polymer blends are formed. Neither Hossainy nor Whitbourne teaches or suggests, expressly or inherently, the step of selecting the second polymer *to be* miscible with the first polymer and, therefore, neither document teaches or suggests all of the method steps recited in Applicants' claims. The Office has failed to identify any portion of the disclosure of either Hossainy or Whitbourne that teaches or suggests selecting a second polymer to be miscible with the first polymer.

The Final Office Action notes that the Perez document—although not formally presented as part of a formal rejection—teaches predicting the miscibility of two polymers based

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on solubility parameters of the polymers. Perez becomes relevant only if there is teaching or suggestion to select polymers based on their miscibility. Without such teaching or suggestion, the skilled artisan has no reason to refer to Perez. As stated in the preceding paragraph, Applicants submit that such teaching or suggestion is missing from both Hossainy and Whitbourne. Moreover, Perez provides no teaching or suggestion that a miscible polymer blend is desirable for delivery of an active agent. Consequently, Applicants submit that Applicants' claims are patentable over Hossainy or Whitbourne, whether alone or in combination with Perez.

Therefore, Applicants submit that the rejection of claims 1-18 and 20-78 under 35 U.S.C. §103(a) as being unpatentable over Hossainy et al. or Whitbourne et al. is improper and should be withdrawn.

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**Summary**

It is respectfully submitted that the pending claims 1-18 and 20-78 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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**CERTIFICATE UNDER 37 CFR §1.10:**

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The undersigned hereby certifies that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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